EXHIBIT 2

Unknown

From: Terry Kilpatrick [TK@ernstlawgroup.com]
Sent: Monday, August 22, 2011 11:08 PM
To: dmb@delphianalytical.com
Cc: mike@jimmywilliamson.com; de@ernstlawgroup.com; Chris Edgington
Subject: Draft declaration
Attachments: Bliesner Declaration mwkdraft.docx; 526 - Actavis P&A's in Support Of MSJ to Exclude General Liability Experts.pdf; Pl. Ex. 500 (Bliesner Expert Report).pdf

Dave –

Based on your conversation with us, we have started a declaration containing the concepts that we discussed and that we would like you to work on. These are essentially our recollection of your comments, so obviously draft whatever you are comfortable with. Would you please begin to draft a declaration that clarifies your opinion and rebuts the comments and argument taken by the Actavis lawyers.

I have also included the Defendants' Motion to Exclude your testimony. See especially page 18 etc.

We are around all day tomorrow so call either Mike Kerensky or myself. Thank you!!!

Terry

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My name is Dr. David Bliesner Ph.D. I do hereby state by and through this declaration to the following facts and opinions. This declaration correctly and truthfully states the facts and opinions that I hold regarding the above referenced case and I do hereby swear under oath to the following:

I have read the Memorandum In Support of Defendants' Motion to Exclude Plaintiffs' General Liability Experts. I respond to the following criticisms made by counsel for the Defendants in the above referenced case as follows;

Defendants argue that "Even though all four (including myself) testify that they believe out of specification product made it to market, not one will testify to a probability that out of specification tablets reached the plaintiffs." (Memorandum in Support of Defendants Motion to Exclude, P. 4) This statement is not true as to my testimony and opinion. It is my opinion, based on a reasonable degree of certainty, i.e. more likely than not, that out of specification Digitek tablets reached the consuming public in 2007 and 2008. Defendants cite to a portion of my deposition in support of this argument that does not support this argument.

> Q. Why, in general, do you think some problem that occurred in 1995, for example, is evidence that defective Digitek got into the hands of consumers in 2007 or 2008?
> A. It's actually fairly straightforward. As I said in the report, primary difficulties in situations like this, in my experience and my opinion is lack of leadership. It's the number one. The people who were running the company back then when they had problems with first consent decree up until just before the second consent decree are same people who are running people the same people on regulatory force, the same people in quality, the same people that caused all the initial problems were still there.

I have reviewed my deposition. I was never asked by counsel for Defendants whether or not I had an opinion based on a reasonable degree of certainty and or more likely than not on whether out of specification product reached the consuming public. I do hold that opinion and a fair reading of my complete report makes this quite clear. The overall systemic failures in the quality systems at Activis, over a long period of time led to a manufacturing process that made it more likely than not the out of specification product would reach the consuming public. The systemic quality system failures at Activis are carefully laid out in my report as follows:

- In December 1990, Actavis initiates a Class II recall for variation in tablet size resulting in sub- and super-potent product. Pl. Ex. M45; Pl. Ex. 500, (Attachments B5, A33).

- In March 1994, the FDA Establishment Inspection Report (EIR) documents numerous quality control problems, including loss of active ingredient during drying and final blending/compression without concern or explanation by Actavis. Pl. Ex. 500, (Attachment A4).

- From 1992-2002, Actavis operates under consent decree (*see supra*) pursuant to which frequent FDA inspections are conducted and numerous Form 483's issued, including repeated findings that quality control procedures are inadequate and not followed, and quality control issues are not properly reported or documented. Pl. Ex. 500, (Attachments B6-B10, B13-19, B21-23); Pl. Exs. 233, 235. Repeatedly, the company's request to lift the consent decree is rejected by the FDA. *Id*.

- During a month-long FDA inspection in October-November 2001, FDA issues Form 483 finding (*inter alia*) "thin" (*i.e*., sub-strength) tablets, rejecting more than 1,600 tablets during a visual inspection. The FDA notes a lack of any assurance that all such defective tablets had been found. Pl. Ex. 236; Pl. Ex. 500, (Attachment A11).

- On June 8, 2004, Actavis confirms a pharmacist's report of a double-thickness/double-weight 0.25 mg Digoxin tablet in the marketplace, from a batch produced seven months prior (November 2003) using tablet presses #67 and 71.[1] Pl. Exs. 241, 242, 128; Pl. Ex. 500, (Attachments A13-A15).

- Following a July-August 2006 facility inspection, the FDA issues a lengthy Form 483 concluding that Actavis has failed to document all laboratory and manufacturing deviations. Pl. Ex. 90; Pl. Ex. 500, (Attachment A18).

- "Summary of Blend Failures 2007" attached to July 2007 e-mail confirms 19 batches of products with blend uniformity failures, including two batches of Digitek. One of these two batches is rejected and one is released. Pl. Ex. 183.

- On April 3, 2007, during its annual product review for the 184 million 0.25 mg Digitek tablets produced in 2006 (44 batches), Actavis confirms 17 Adverse Drug Events (including elevated Digoxin blood levels and an "unknown" potency question) and blend uniformity defects, particularly with respect to batch no. 60319A. Pl. Ex. 253; Pl. Ex. 500, (Attachment A27).

- On May 22, 2007, Actavis' records confirm discovery of out-of-specification Digitek with respect to weight in batch no. 5453A (produced in 2005). Pl. Ex. 500, (Attachment A26); Pl. Ex. 501, (Bates No. ACTAV001420149).

- On November 30, 2007, 20 defective double-thickness tablets are discovered by Actavis during packaging of batch no. 70924A1, scattered randomly throughout the batch.

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Discovery is not made through any quality control process or method, but merely a lucky observation by a line worker. Following a rapidly conducted visual inspection, the product is released to market on December 5, 2007, without conclusive evidence of the cause of the defect. Pl. Exs. 44, 16; Pl. Ex. 500, (Attachments A31-32), *and see, II.A.1, supra*.

- In late 2007, Actavis investigates another blending failure with respect to Digoxin batch nos. 70148A and 70207A, this time attributed (by Actavis) to various potential causes, including dry (low humidity) conditions during winter and variation in API particle size. Pl. Ex. 159; Pl. Ex. 500, (Attachment A34).

- In January 2008, internal e-mail at Mylan (a Digitek distributor), confirms two batches of Digitek 0.125 mg tablets with out-of-specification assays (too low). Pl. Ex. M14; Pl. Ex. 500, (Attachment A52).

- On February 20, 2008, Actavis' Investigation No. 08-030 confirms discovery of out-of-specification (sub-thickness) tablets in bucket no. 2 of batch no. 80133A, 0.25 mg Digitek. Pl. Ex. 217, (p. 5); Pl. Ex. 500, (Attachment A54).

- In March 2008, an investigation report by UDL, another Digitek distributor, recounts the complaint (then pending further investigation) of a consumer who received tablets smaller than usual, causing her heart to race. Pl. Ex. M69; Pl. Ex. 500, (Attachment A36).

- On April 1, 2008, packaged overweight 0.125 mg Digoxin tablets are discovered towards the end of batch no. 80228A1, (bucket nos. 26 and 27). In a single 5,000 count bottle, 17 out of 30 pills inspected are of excess weight, and 17 out of 50 tablets are in excess of 120 mg, at least 10.9% in excess of the high end of Actavis weight specification. Pl. Ex. 141; Pl. Ex. 500, (Attachment A39); *and compare* Pl. Ex. 16, (p.4, weight specifications).
- From March-May 2008, the FDA inspects Actavis facilities due to "significant cGMP deficiencies" relating to the prevention and remediation of double-thick tablets and blending failures. *See, II.A.3, below*. This inspection ultimately prompts the Digitek recall. *See, II.A.3-4, below*.

- On April 24, 2008, a Class I nationwide recall of all Digitek tablets manufactured by Actavis is announced, due to double-thickness tablets, overweight tablets, and/or blending defects. *See, II.A.4, below*; Pl. Ex. 113; Pl. Ex. 500, (Attachment A35). Simultaneously, production and shipment of all Actavis products (not just Digitek) is suspended. Pl. Ex. 502, (pp.20-27).

- In late April 2008, just days after notice of the Digitek recall, Mylan confirms that a Digitek tablet "obviously of double thickness" is reported to have been discovered by the

staff of a Massachusetts nursing facility. Doc. No. 527-1, (Page ID# 12224).[2] There is no indication that any effort was made by defendants to specifically preserve this defective tablet, which is now reportedly missing. Doc. Nos. 527, 527-1.

- In August 2008, Actavis expands its product recall still further to encompass all 66 products manufactured at its Little Falls, New Jersey facility, (the same facility where Mr. McCornack's Digitek was produced). Pl. Ex. 500, (Attachment B43).

- Starting in December 2008, Actavis is once again operating under a consent decree, establishing strict management controls over Actavis' facilities. Pl. Ex. 21; Pl. Ex. 500, (Attachment A47).

- Actavis' annual product review for 0.125 mg Digitek tablets produced in 2008 confirms rejection of 8 out of 19 batches, largely in connection with the FDA's March-May 2008 inspection and Digitek recall, including one batch rejected because the tablets were out-of-specification for weight. Pl. Ex. 144, pp. 4-5; Pl. Ex. 500, (Attachment A48).

- Actavis' January 2009 Quality Review Board report confirms that from August 2008 through January 2009, Actavis received nine complaints of double-thickness Digoxin tablets found in the marketplace. Pl. Ex. 73.

As pointed out in my report, I have extensive experience regarding the development and implementation of quality systems that are necessary to translate validated good manufacturing practices into actual performance that minimizes the risk that out of specification and potentially dangerous drugs reach the market place. Quality Systems is a term of art in the pharmaceutical world. It is that overall system that is necessary to insure that good manufacturing practices are followed but more importantly, when they fail, call for prompt, honest, comprehensive responses to identify the problem and find a solution. A large part of my expertise involves evaluating and developing these quality systems for the pharmaceutical industry. It is this expertise that I brought to bear on the issues presented by the particular instance of Activis' out of specification Digitek tablets being manufactured and shipped to the market. In my opinion, the facts set out above reflect a systemic, long term, break down of the quality systems in general at Activis and this breakdown was a cause of the manufacture of out of specification Digitek tablets. Moreover, this breakdown of the Activis quality systems made it more likely than not that out of specification Digitek tablets made it to the market place. Not only are quality systems designed to prevent the manufacture of out of specification products in the first place, they are also relied upon to detect and prevent out of specification products from being packed and shipped. When the quality system is broken, as it clearly was at Activis over a long period of time, out of specification product is more likely to be manufactured and more likely to go undetected and shipped to the public. My examination of the documents demonstrating Activis' repeated quality systems failure, which is reflective of a lack of respect for the quality systems from management down through the organization, made it highly likely that once an out of specification tablet was manufactured at Activis in 2008, no matter what the product, some of the out of specification

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product would make it through the broken quality system and into the market place. This is the type of analysis I made in this case. I had more than ample evidence of a broken quality system upon which to base my conclusions. This type of analysis is well within my expertise. It is a component of what I do for all my clients.

Activis criticizes the data base upon which I base my conclusions. They argue that I did not examine the same types of documents that I would examine if I were to perform the same type of analysis for a private client. This criticism is born of a fundamental misunderstanding of what is done in the pharmaceutical industry and what I do for my clients. For example, Activis takes a portion of my deposition out of context where I explain that if a client asked me to perform a "comprehensive analysis of GNPs" (Good Manufacturing Practices) I would expect the client to give me full access to "production records". My response to that specific question was correct. If the client wanted me to do a comprehensive analysis of their production performance specifically, of course I would expect to look at the production records. What Activis seems to not understand, probably disingenuously, is that the analysis I was asked to do in this case concerned the overall quality systems of Activis, not an analysis of the production track record. It is known that Activis had a problem with its production of Digitek in 2008. That is why the company recalled 159 batches and millions of tablets after the FDA was advised of the discovery of 20 double thick tablets. The analysis I was asked to do and did in this case was a much broader analysis of why the quality systems at Activis broke down and yielded this out of specification result. I was asked to evaluate Activis' quality systems for the root cause of this undeniable breakdown of the validated good manufacturing practices that were to be employed at Activis. I examined overall company approach and implementation of their quality systems and discovered that they were over a long period of time impotent, unreliable, not taken seriously by upper management and in the final analysis inadequate to protect the consuming public from out of specification product reaching the consuming public. While this type of analysis is a component of what I generally do for any given client, it is generally only part of my analysis. Of course, when I am employed by a client, I have access to more records and can do a more comprehensive analysis of the entire manufacturing process. This is generally necessary for my clients because in addition to the identification of problems, my clients are also asking for solutions. Solution to the problems does require a more detailed analysis of the records and access to more records. I was not charged to do this type of "comprehensive analysis" of the entire manufacturing process in this case nor was such and analysis possible. Activis was not my client. I did not have unfettered access to their records. I was not asked to define or suggest a solution to their long standing lack of quality systems problem. I was asked to evaluate and quantify the nature and extent of the disfunction of Activis' quality systems problem and offer an opinion on what role, if any, that breakdown had on the manufacture of out of specification Digitek in 2008 and whether or not as a result of the lack of quality systems, it was more likely than not that Digitek product actually made it to the market place. My unequivocal opinion, after conducting this focused analysis of the Activis quality systems, or lack thereof, was that Activis' failure to make the implementation and enforcement of its quality systems a company priority was a direct cause of the manufacture of out of specification Digitek and likely led to the dissemination of that dangerous product to the consuming public.

Activis also argues that the only evidence upon which I base my opinion that Digitek made it to the market place in 2008 is a single report in approximately 2003 from a pharmacist of a double thick tablet in a blister pack. This is not true. To be totally accurate, the pharmacists report of the blister pack anomaly was not the only report of an out of speck Digitek tablet. There was at least one other report in 2008 of a distributor of Digitek, Mylan, confirming that a Digitek tablet "obviously of double thickness" was reported to have been discovered by the staff of a Massachusetts nursing facility. Doc. No. 527-1, (Page ID# 12224). However, the evidence upon which I rely in opining that it is more likely than not that Digitek reached the market place is largely found in Activis' history of a lack of concern for quality systems both before and after the recall of Digitek. I have detailed the long history of a lack of concern for quality systems at Activis prior to the recall of Digitek in 2008 above. Of equal concern is the lack of the application of quality systems principles after the discovery of the double thick Digitek tablets in 2008. Digitek claims to have visually inspected the single batch of approximately 4.8 million tablets and found 20 tablets that were admittedly double thick. Activis was satisfied with this visual inspection and shipped the batch. The suggestion that a visual inspection of 4.8 million tablets is sufficient to discover and remove all the double thick tablets is contrary to the most fundamental concepts of quality systems management. The obvious chance that human error in this visual inspection could miss or overlook other out of specification tablets is inescapable. Further, after the recall, Activis did not test, examine or do anything to determine the magnitude of their manufacturing problem of out of specification Digitek tablets. The simply stored the recalled product in a warehouse and kept on producing Digitek. Remembering that Activis was unable to determine the root cause of the manufacture of the double thick tablets that they found, the lack of further investigation by examining the recalled product is indicative again of the conscious indifference of Activis for quality systems safeguards. Apparently they did not want to know the answer to the question of how many out of specification tablets were shipped. The number of out of specification tablets in the recalled product would have been an indication of whether or not further examination of the root cause was necessary. This indifference jumps out at me as a quality systems professional in the pharmaceutical industry. All this leads me to the conclusion that the quality systems at Activis were not working properly. The quality systems, as explained in my report, is the last line of defense for a manufacturer to prevent out of specification product from being manufactured and shipped. The lack of reports from the field of out of specification tablets is not surprising, especially from persons who are making the claim that they were injured. If they were injured by the out of specification tablet, that means that they must have taken it. If they took it, it was gone for ever. All this lack of concern for quality systems and protection of the consuming public, in addition to the two reports of out of specification Digitek tablets in the field is the whole of the basis of my opinion that Digitek tablets, more likely than not, reached the consuming public.

Activis further claims that I have admitted that I am not an expert in the field of recalls. They make this assertion by misconstruing a passage in my deposition concerning recalls. In this series of questions, I tried to explain to Activis lawyers the difference between coming to the conclusion that out of specification product may have reached the consuming public and a recall experts work in then analyzing how much product that may be out of specification was shipped and what the scope of the recall should be according the assessment of the risk. The latter part of that analysis, the nature and scope of a recall, is a very specialized field and calls for an expertise

that I admittedly do not possess. I am however qualified to make an assessment of whether or not the quality systems at a company have failed to such a degree to make it likely that some product may have been shipped to the public. When I said I was not a recall expert, I meant exactly what I said. That does not mean that I do not have the expertise to make an assessment of a company's quality system performance for the purpose of assessing the risk of whether or not adulterated or out of specification product has been shipped to the market place. That is part of what I do and well within my professional expertise and experience as demonstrated by my C.V..

As reflected in my expert report, it is my opinion that more likely than not, Actavis manufactured 0.125 and 0.25 mg. tablets of Digitek that contained twice the active ingredient of digoxin and/or were twice the normal thickness, and that these tablets were released to the public in 2007 and 2008.

The basis for my opinion is set forth in my expert report, but essentially, there was a complete failure of the Quality System as evidenced by the numerous instances where cGMPs were not implemented and/or followed, and by the numerous instances where in fact, out-of-specification tablets were discovered only after they had been released by Actavis or its predecessor Amide Pharmaceuticals. One glaring example includes the procedures used by Actavis concerning the manufacture of double-thick tablets that eventually led to the recall of all digoxin products in April 2008. In that case, Actavis used a visual inspection to try to locate out-of-specification tablets that they suspected were contained in both packaged and unpackaged product. The "visual inspection" that Actavis used was completely inadequate. It was not a qualified CGMP and therefore no assurance can be made that it was effective at locating all double thick tablets in any respect. Further, based on my years of experience and my knowledge that there is no qualified procedure for the visual inspection employed by the Actavis employees, it would have been extremely difficult or impossible for individuals to spot double thick tablets by keeping a "watchful eye" as the tablets traveled down the bottle filler channels, and equally unlikely to be able to visually spot other tablets poured out of 5,000 count bottles onto a table top. Actavis never determined a root cause for the tablet error, but nevertheless released both the batch that it knew had failed, as well as the batches produced before and after that batch, in violation of their own CGMPs. Because there was no validated process for insuring that all double thick tablets had been identified, it is my opinion that more likely than not, more than 20 defective tablets were produced during the batch run and that these additional defective tablets were never located before they were released to the general public. Despite repeated assurances by Actavis that it would replace the presses that produced the double thick tablets, this was never accomplished to the best of my knowledge. Based on this and the many other instances of CGMP violations, it is my opinion that more likely than not, the same types of manufacturing errors had been occurring before, during, and after this known violation for both 0.125 and 0.25 mg Digitek tablets and that more likely than not, double thick tablets were released to the consumer as a result.

ADDITIONAL NOTES FROM CONVERSATION

Other reasons to support opinion:

problems with the process.....no corrective action taken
problems with the personnel....no changes
no cause of double thick tablets discovered...therefore no corrective action taken
visual inspection only is crude method of detection
4.8 million visual inspection is not reliable to determine rate of out of spec tablets
no inspection of recalled tablets to determine rate of out of spec
could be done by automated method to determine rate....
Failure to determine rate of out of spec from recalled product is telling...
Visual techniques not adequate to catch them all.

comprehensive review of compliance with the GMPs

Comprehensive review GMPs for client calls for identification of problem and the solution to those problems. Even when you have cooperation of the client who opens their facility and records to you, it is impossible to review all the records.

Production Records, can't do a general assessment of GMPs ***that includes the production system*** w/o production records:

I was not doing a specific assessment of the production system or a general assessment of the GNP. I was doing a broader assessment of the quality assurance systems in place to prevent OOS/defective product into the market place.

This exercise is limited to determining whether Activis had sufficient quality control procedures and whether the flaws in the quality control procedures probably allowed dangerous product to get into the market place....essentially half of a comprehensive review for a client.
I am not a recall expert.

I am qualified to render an opinion on whether or not the quality systems failure resulted in oos/defective product getting to the market.
Somebody else would have to assess how much got to market, which lots to recall and the details of the recall after we determine that oos/defective product was probably in the market.

Didn't look at batch records, FDA 484s, etc.....

The test of whether the quality system of a company is robust enough to protect the public from OOS/defective pharmcueticals is how it acts when things go wrong, not when things go right.